

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

USDC SDNY
DOCUMENT
ELECTRONICALLY FILED
DOC #:
DATE FILED: 05/03/2022

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(RC) 2 PHARMA CONNECT, LLC,

Plaintiff,

-v-

MISSION PHARMACAL COMPANY,

Defendant.
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21-cv-11096 (LJL)

ORDER

LEWIS J. LIMAN, United States District Judge:

The Court is in receipt of the parties' letters at Dkt. Nos. 67–69 addressing Plaintiff (RC) 2's proposed redactions to Exhibit C to the declaration of Jason Raff, Dkt. No. 62-3, as well as the documents that are subject to (RC) 2's other pending motions to seal.

The limited sealing requests outlined in Dkt. No. 69 are GRANTED, with specific exceptions in Dkt. Nos. 28-5; 28-7; and 28-9; those exceptions are specified in the attached pages. Dkt. No. 8-5, as to which the parties did not provide proposed redactions, should be redacted only to conform with Dkt. No. 28-8.

The parties are directed to ensure that all the documents as to which the motions to seal have been withdrawn and any documents as to which motions to seal were previously filed but which are not addressed in Dkt. No. 69 are filed in full on the public docket and that all the documents addressed in this Order are filed on the public docket with only the limited redactions approved herein by May 10, 2022.

The Clerk of Court is respectfully directed to close the pending sealing motions at Dkt. Nos. 6, 26.

SO ORDERED.

Dated: May 3, 2022

New York, New York



LEWIS J. LIMAN
United States District Judge

Exhibit C – Manufacturing and Supply Terms

RC2 Pharma Connect, LLC Business Terms for the manufacturing and packaging of Docosanol 10% Cream		
1.	Parties	Mission & RC2 Pharma Connect, LLC
2.	Type of agreement	Product Manufacture and Supply Agreement for the Territory (the “Definitive Agreement”)
3.	Products	Docosanol 10% Cream (2g Tube, 2g Pump)
4.	Territory	The United States of America, its territories and possessions (the “Territory”) and future Territories decided by mutual consent of both parties.
5.	Active Pharma Ingredient (API)	The API for Docosanol 10% Cream (Docosanol) will be supplied by Mission Pharmacal for commercial supplies of the Product.
6.	API and Finished Product Testing	Active ingredient testing and Finished Product will be tested by Mission as per the agreed Specifications
7.	Forecast	Estimated annual Forecast: i. [REDACTED]
8.	Batch size & Yield	[REDACTED]
9.	Commercial Terms	a. Price per bottle: As per Annex A b. Shipment Terms: EXW Mission Facility (Boerne) c. Payment Terms: 30 days from the date of receipt of Product [REDACTED]
10.	Quality Agreement	Prior to first delivery of Product to RC2 Pharma Connect, LLC, the Parties shall enter into a quality agreement (the “Quality Agreement”) containing terms and conditions standard and customary for a manufacturing and supply agreement of this nature, including, without limitation, product release, product recalls, complaints, audit rights, interactions with government agencies, record retention and returns.
11.	Term	The initial term of the Definitive Agreement shall be [REDACTED] years after commercialization of the Product by RC2 Pharma Connect, LLC. In the event that Mission has been in compliance with the terms of the Definitive Agreement and experienced no substantial interruptions, the Definitive Agreement shall automatically renew for [REDACTED] year periods after the initial term and shall continue renewing, unless terminated by either party with nine (9) months prior written notice.
12.	Termination	Customary termination rights to be agreed upon by the parties in the Definitive Agreement
13.	Diligence	Both Parties shall undertake their respective responsibilities under the agreement in a business-like way and according to recognized standards.
14.	Confidentiality	This Term Sheet, and the information contained herein, constitutes as “Confidential Information” as defined in the confidentiality agreement between RC2 Pharma Connect, LLC and Mission Pharmacal dated Month/Day/Year (“Confidentiality Agreement”)
15.	Governing Law	The State of Texas, the United States of America. Each party waives any right to a

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Docosanol Team Meeting:

Mission Pharmacal & RC2

Meeting Date:

Wed. June 24, 2021

Meeting Time:

9:30am – 10:30am Central Time

Location:

Webex Call In:
(see calendar invite)

Agenda Items

Attendees: [Mission] Brianne McEwen, Zoey Dawson, Jon Taylor, Nikunj Patel, Lonnie Wright, Jerry Stock, David Wheat
[RC2] Dwight Raff, Jason Raff, Bill Cain [REDACTED]

Discussion Points:

1. IVRT Method Validation: updated protocol provided 6/22 for review
2. Related Substance Method Validation: update on timing
3. Water Content Method: interference with humidity and protocol for revising the current method
4. 1st Registration Batch 39X21 summary with recommendation to proceed.

- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

5. 2nd Registration Batch 40X21 compounded 6/22.

- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

6. 3rd Registration Batch 41X21 started compounding today, 6/24. Filling scheduled for next week on 6/30-7/1.

7. Stability Protocols [REDACTED]

8. Extractable/Leachable Study: Contact made with Stira for CDA.
9. Polymorph analysis request for quote from SWRI.
10. Regulatory Filing Support.
11. Secondary Packaging: Carton and PI design
12. Other/Open Discussion

Meeting Notes:

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6.	API and Finished Product Testing	Active ingredient testing and Finished Product will be tested by Mission as per the agreed Specifications
7.	Forecast	Estimated annual Forecast: <ul style="list-style-type: none"> 2g Tubes- [REDACTED] 2g Pumps- [REDACTED]
8.	Batch size & Yield	[REDACTED]
9.	Commercial Terms	a. Price per bottle: As per Annex A b. Shipment Terms: EXW Mission Facility (Boerne) c. Payment Terms: 30 days from the date of receipt of Product [REDACTED]
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